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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,454	02/02/2001	Gregorio del Val	2001-0705	9327

7590

04/24/2002

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 04/24/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/776,454

Applicant(s)

VAL ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 13-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Non-Final Rejection

Claims 1-12 are pending examination.

Applicant's election with traverse of Group I (claims 1, 2, 5, 6, 7, 8, 9, 10, 11, and 12) and species "applying to the skin of a newborn dog" in claim 1, step a) in Paper No. 8 filed on 2/13/02 is acknowledged.

In addition, applicants do not fully respond to election/restriction paper no. 7. Examiner called applicants' representative, Michael Ward on 3/12/02 and notified Mr. Ward of the missing election of species in claim 2. Mr. Ward elected step a) skin test in claim 2 with traverse on 3/12/02.

The traversal is not found persuasive because the applicants did not described the reason(s) for the traversal.

The requirement is still deemed proper and is therefore made FINAL.

In addition, after further examination, claims 3 and 4 read on the elected embodiment and the claims will be rejoined with the elected invention. Furthermore, after a search of the prior art, the method is novel and the non-elected species in claim 1 and claim 2 will be rejoined with the elected invention.

Claims 13-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

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The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because the abstract exceeds 150 words in length. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: a line through the word "dog" on page 11, line 19.

Clarification is required.

Claim Objections

Claims 1, 4, and 9-10 are objected to because of the following informalities: Claims 1, 9, and 10 read on a non-elected invention (transgenic animal). Claims 1 and 4 should have a comma before the conjunction "and" or "or". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. Steps comprising comparing the degree of a reaction observed

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by challenging a dog with an extract using a specific test (e.g. skin test) to a control extract using the same test is considered critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The claimed invention encompasses "A method for testing the allergenicity of a heterologous protein produced by a plant that had been genetically modified to produce the protein, comprising the following steps: (a) sensitizing a newborn dog from an atopic dog colony with a first extract prepared from tissue of the genetically modified plant, containing a mixture of plant proteins and the heterologous protein, by applying the extract to the skin of the newborn dog, (b) after a period sufficient to allow the dog to establish an immune response to the extract, challenging the dog with the extract, (c) observing the degree of allergic response provoked, (d) if a detectable skin reaction is observed, comparing the degree of skin reaction observed with that observed by carrying out steps (a)-(c) above, but where the sensitizing step (a) or applying step (b) is carried out with a control plant containing the same proteins as the first extract but lacking the heterologous protein, and (e) if the degree of skin reaction at (c) is greater than that observed by carrying out steps (a)-(c) in accordance with step (d), identifying the heterologous protein as a potential allergen in humans" (page 32). It appears from the specification that the active step for determining a degree of allergic response of a heterologous protein isolated from a genetically modified plant is by comparing the allergic response from a specific test (e.g. skin test) to a control extract using the same test. More specifically, the as-filed specification teaches that each test requires a different step for observing the degree of allergic response (pages 13-15). The claimed invention contemplates using several different allergy tests and the claims only

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encompass a method of using a specific test (skin test). Therefore, the steps for any other allergy test are incomplete and in view of *In re Mayhew*, the claims are not enabled by the disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 2, 9, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it reads on a non-elected invention (heterologous protein produced by a transgenic animal). The claim recites “the genetically modified plant **or** animal **and** containing a mixture of plant **or** animal proteins **and** the heterologous protein.” In addition, the claim is indefinite because the claim does not define the define what the is the elected invention because the claim encompasses containing a mixture of plant **and** the heterologous protein; animal proteins **and** the heterologous protein; a mixture of plant **or** animal proteins **and** the heterologous protein. If the applicants intend to claim a mixture of plant **and** the heterologous protein, then the claim should read on the elected invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the active step for determining the degree of allergic response of a heterologous protein isolated from a genetically modified plant is by comparing the allergic response from a specific test (e.g. skin test, feeding test, gastroendoscopy test, inhalation test, and transdermal patch test) to a control using the same test. Therefore, the metes and bounds of the phrase “degree of an allergic” cannot be defined because each test other than the skin test

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does not have a response from a control, so that one skilled in the art could determine the degree of allergic response provoked.

Claim 2 recites the limitation "the allergen material" in line 24, page 32. There is insufficient antecedent basis for this limitation in the claim. There are many allergen materials known in the art and the claim does not define which allergen material is being claimed.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. Claim 9 refers to the protein of claim 1 produced by an organism other than the transgenic plant or animal; however, the protein in claim 1 is produced by a transgenic plant or a transgenic animal (non-elected invention). Claim 9 is broader than the scope of claim 1, on which it depends.

Claim 11 recites the limitation "the protein" in line 28, page 33. There is insufficient antecedent basis for this limitation in the claim. There are many proteins in the dog sensitized with the extract and the disclosure does not define what protein is being used in the claimed invention. Clarification is requested.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, because the elected invention is a method of testing the allergenicity of a heterologous protein produced by a genetically modified plant and the last step of the invention is step e) and claim 11 is separating proteins in the extract and testing each protein with an undefined immunoglobulin. The claim does not define what immunoglobulin is obtained and used from the dog. There are numerous immunoglobulins in the dog and the disclosure does not define the metes and bounds of what immunoglobulin is claimed. In addition, it is not apparent how claim 11 is operatively linked to the pre-amble of claim 1 since step e) of claim 1 completes the last step of the invention.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, primary examiner, Dave Nguyen can be reached at (703) 305-2024.

If attempts to reach the primary examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635
4/19/02

DAVE T. NGUYEN
PRIMARY EXAMINER

